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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/141,017	10/26/1993	EUGENE P. GOLDBERG	4733	7268
181 7590 05/27/2008 MILES & STOCKBRIDGE PC 1751 PINNACLE DRIVE SUITE 500 MCLEAN, VA 22102-3833				
EXAMINER FISHER, ABIGAIL L				
ART UNIT 1616		PAPER NUMBER		
NOTIFICATION DATE 05/27/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

08/141,017

Applicant(s)

GOLDBERG ET AL.

Examiner

ABIGAIL FISHER

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date: _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Amendments/Remarks filed on February 29 2008 is acknowledged. Claim 2 stands cancelled. Claims 1, 4 and 6 were amended. Claims 1, 3-7 are pending.

Terminal Disclaimer

The terminal disclaimer filed on March 12 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5140012979, 6010692, 6464970, 6706780, and 5350573 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimer filed on April 12 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5080893 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 as currently written claims that the polymer is hyaluronic acid indicating all forms and molecular weights.

However, claim 1 excludes hyaluronic acid with molecular weights above about 1,500,000. Therefore, claim 5 is broader than claim 1 and fails to further limit the subject matter of claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 as currently written is vague and indefinite. It is unclear what hyaluronic acid applicant is claiming. Claim 1 specifically excludes hyaluronic acid with molecular weights above about 1,500,000. However claim 5 as currently written includes all forms and molecular weights of hyaluronic acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (US Patent No. 4819617).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue

Art Unit: 1616

during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

Goldberg et al. is directed to solutions when employed as ophthalmic viscosurgical materials in the eye protect the surrounding sensitive tissue during surgery (column 2, lines 34-37). The solutions comprise carboxymethylcellulose (CMC) derivatives such as sodium carboxymethyl-cellulose, having a molecular weight greater than 500,000 (column 1, lines 58-59). CMC solutions of 2.2 to 4.2% were shown to perform excellently in intraocular implant surgery with good tissue protection (column 3-4, lines 67-68 and 1-2). The CMC may be dissolved in any physiologically acceptable solution such as saline or buffered saline (column 4, lines 18-21). Saline is necessarily an aqueous solution.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Goldberg et al. does not specify that the solutions of the invention can be utilized in a method of protecting tissue and reducing tissue damage in surgery. However, Goldberg et al. does indicate that the solutions perform excellently in intraocular implant

Art Unit: 1616

surgery with good tissue protection and the solutions protect the surrounding sensitive tissue during eye surgery.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to utilize the solutions of Goldberg et al. in a method of protecting tissue and reducing tissue damage in surgery. One of ordinary skill in the art would have been motivated to utilize this solution in protecting tissue and reducing tissue damage because Goldberg et al. indicate that these solutions provide tissue protection and protect the sensitive tissue in the eye during surgery. Therefore, based on the teachings of Goldberg et al. one of ordinary skill in the art would have a reasonable expectation of success in utilizing the solution in a method of protecting tissue and reducing tissue damage in surgery.

Regarding claim 6, applicant claims broad surgical classes. Goldberg et al. indicates that the solutions perform excellently in implant surgery, which falls under the general surgery class plastic or reconstructive.

Claims 1, 4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (US Patent No. 4585666) in view of Schwartz et al. (US Patent No. 4589873).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue

Art Unit: 1616

during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

Lambert is directed to a coating for a polymer surface. The hydrophilic coating has a low coefficient of friction (column 1, lines 8-10). Examples 1 and 2 are directed to coating a urinary catheter. The catheter is dipped in a PVP solution and then cured above a bowl filled with water. It is disclosed that the presence of water during the curing process is to help bind the hydrophilic PVP (column 2, lines 53-67). The PVP is utilized in a solution from 0.5 to 10% (column 2, lines 49-51). The molecular weight of the PVP is from 10^4 to 10^7 (column 2, lines 41-42). Other surfaces that may be coated include latex rubber (column 1, line 56).

**Ascertainment of the Difference Between the Prior Art and the Claims
(MPEP §2141.012)**

Lambert et al. does not specify that the PVP can be dissolved in water. However, this deficiency is cured by Schwartz et al.

Schwartz et al. indicates that the hydrophilic polymer PVP is water soluble (column 1, lines 49-50).

**Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to combine the teachings of Lambert et al. and Schwartz et al. and dissolve the PVP in water. One of ordinary skill in the art would have been motivated to utilize water as the solvent which to dissolve PVP because Schwartz et al. teach that PVP is water soluble. Additionally, since water is utilized in the curing process of Lambert et al., utilizing water as the solvent which to dissolve PVP would eliminate the step of having to remove a different solvent and one could go immediately from coating to curing.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding claim 6, applicant claims broad surgical classes. Schwartz et al. teach that the PVP solution can be utilized to coat latex rubber, such as rubber gloves. Gloves would be utilized in every type of surgery as they are a necessary component of a surgical procedure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

Art Unit: 1616

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, and 6-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-14 of U.S. Patent No. 4819617. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Patent '617 claims an ophthalmic surgical procedure where in the anterior chamber of the eye is filled with a protective surgical material comprising an aqueous

solution of at least 1.5% by weight of a physiologically acceptable water soluble carboxymethylcellulose or salt thereof having a molecular weight greater than 500,000. The surgery as claimed comprises intraocular lens implantation.

Patent '617 does not claim a method of protecting tissue or reducing tissue damage in surgery comprising the protective surgical material.

It would have been obvious to one of ordinary skill in the art to utilize the protective surgical material of Patent '617 in a method of protecting tissue and reducing tissue damage in surgery. One of ordinary skill in the art would have been motivated to utilize this solution in protecting tissue and reducing tissue damage because Patent '617 indicate that these solutions provide tissue protection and protect the sensitive tissue in the eye during surgery. Therefore, based on the teachings of Patent '617 one of ordinary skill in the art would have a reasonable expectation of success in utilizing the solution in a method of protecting tissue and reducing tissue damage in surgery.

Regarding instant claim 6, applicant claims broad surgical classes. Patent '617 claims that the surgery comprises intraocular lens implantation, which falls under the general surgery class plastic or reconstructive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/

Primary Examiner
Art Unit 1616